

ONE HUNDRED NINTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON GOVERNMENT REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6143

Majority (202) 225-5074
Minority (202) 225-5051

February 15, 2005

The Honorable Lester Crawford, D.V.M, Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

I am writing regarding the FDA Budget for FY 2006. Under the budget proposed by the Administration, the number of FDA employees would decline, reducing the Agency's inspection and enforcement capacity.¹

During budget briefings, HHS staff indicated that the cuts did not reflect a considered judgment about specific positions that could be eliminated without hurting FDA functions. Instead, the cuts simply reflect the fact that the budget fails to provide adequate funding for existing employees.

These personnel cuts would have a potentially significant impact on American consumers. Documents submitted by FDA indicate that the proposed budget would result in cuts in the number of domestic and foreign food safety inspections, cosmetics inspections, foreign and domestic drug inspections, and inspections of biologic products and vaccines.²

My concern about these cuts is exacerbated by FDA's recent enforcement record, which shows that the agency has been unable to adequately protect consumers in important areas. In recent months, there have been several high profile drugs pulled from the market because of safety concerns that were not addressed by the Agency.³ The country faced severe shortfalls of flu vaccine because of the agency's inability to adequately address problems at Chiron, the

¹ HHS, *Budget in Brief, Fiscal Year 2006* (Feb. 2005). The budget would eliminate 204 FDA employees, a 2% decline.

² FDA, *FY 2006 Budget*, pp. 323-328 (Feb. 2005).

³ Senate Committee on Finance, *FDA, Merck and Vioxx: Putting Patient Safety First?* (Nov. 18, 2004).

The Honorable Lester Crawford, D.V.M, Ph.D.
February 15, 2005
Page 2

manufacturer of the vaccine.⁴ And several recent studies have shown that overall enforcement in areas such as drug advertising and biologic and vaccine manufacturing, has declined by over 70% in recent years.⁵

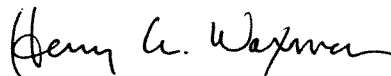
Now is not the time to for additional cuts in FDA enforcement resources. But the President's proposed budget would result in a further reduction in enforcement capacity.

In light of these problems, I am writing to request that you provide me with additional information on the 2006 budget. Please provide:

1. Documents prepared by FDA that describe the Agency's enforcement and inspection priorities, and how these will be impacted by the proposed budget cuts.
2. Information describing the impact of the proposed budget cuts on bioterrorism preparedness. Please provide specifically (a) the number of FDA inspectors added to perform imported food inspections as a result of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and other legislation passed by Congress in the wake of September 11, 2001, (b) the total number of inspectors conducting such inspections who were added or subtracted in each subsequent year, (c) the number of such inspectors that will be added or subtracted under the proposed 2006 budget, and (d) the total number of imported food examinations conducted in each fiscal year from 2002-2005, and how many will be conducted under the proposed 2006 budget.
3. Budget documents that describe alternative scenarios, including information on the estimated FDA budget that would be required to maintain inspections and enforcement at existing levels.

Please provide me with this information by March 1, 2005. The staff contact for this request is Brian Cohen at (202) 225-5051.

Sincerely,



Henry A. Waxman
Ranking Minority Member

⁴ House Committee on Government Reform, *The Nation's Flu Shot Shortage: Where Are We Today and How Prepared Are We for Tomorrow?* (Nov. 17, 2004).

⁵ House Committee on Government Reform, Minority Staff, *The Decline in FDA Enforcement* (Feb. 2005).